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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,162	10/03/2006	Hughes Jaccard	2006_1323A	6061

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EXAMINER	
BERCH, MARK L	

ART UNIT	PAPER NUMBER
1624	

NOTIFICATION DATE	DELIVERY MODE
06/16/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/591,162	JACCARD ET AL.	
	Examiner	Art Unit	
	Mark L. Berch	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-22 and 44-47* is/are pending in the application.

4a) Of the above claim(s) ____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-22 and 44-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Removing X=S eliminates Noell, and Baer. Requiring that bonding of X be in the 6-position eliminates Baker. Requiring that a substituent be present at the 8-position or 9-position eliminates Keppler.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4, and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Zheng, with Calnan or 20100105053 supplemental.

Requiring that there must be a substituent at the 8-position or 9-position eliminates the first 6 compounds of figure 1.

But in addition, there are the benzylated versions 6a, 6b, 6c, 1a. 1b, and 1c, in which R1=benzyl, as was discussed previously.

The traverse is unpersuasive. The remarks assert that R1 cannot be benzyl. If this is true then the reference does not anticipate, but this is not agreed with.

R1 can be –R2-L2, and R2 can be methylene, so the question is whether L2 can be phenyl. The last choice for L2 provides for any parts of the HIV tat-protein sequence. The part appears without limitation. The phenyl ring appears as a part of the amino acid Phe, and Phe is part of the HIV tat-protein sequence, as is shown by Calnan, which shows Phe^{32}

and Phe[38]. See Figure 1. In addition, the phenyl ring is part of Tyr, which appears as Tyr[26] and Tyr[47].

In addition, phenyl qualifies for the first L1 choice of "spectroscopic probe". The term is not specifically defined in the specification. The examiner cites 20100105053 which states on paragraph 35: "The term "spectroscopic probe" as used herein indicates any substance that is suitable to be detected based on an interaction between a radiation and the substance through a spectroscopic instrument." It is thus a very broad term. The protons of the phenyl ring can be detected via PMR, the C-C bonds and C-H can be detected via IR, and as is true for aromatic rings generally, the ring itself absorbs in the ultraviolet, and Raman spectrum (typically done as FT-Raman) can be obtained for the phenyl group as well.

Claims 1-2, 4, and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Vaidyanathan.

See compounds [^{18}F]6 in scheme 1, and compounds 6-13 on page 872, including the radio-iodinated version of 7 at the end of scheme 2. The rejection is similar to above, with the amino qualifying as R1 is all compounds.

The traverse is unpersuasive. Applicants argue that the trimethylsilylethyloxymethyl group of the reference does not qualify as R1. The ethyloxymethyl, or the methylene qualifies for R2, and the remaining trimethylsilylethyloxy or trimethylsilyl meets the definition of "spectroscopic probe". The TMS group of course can be detected by NMR and indeed is used for exactly that purpose, and either group can be seen in the IR as well.

Claims 1-2, 4, 6-9 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Damoiseaux.

See type 2, represented by compound 8. These are guanine based oligonucleotide with X=O with the biotin substituent at the right end being the L1 label, with the amino qualifying as R1. In addition, the amide linkages in 2 would also qualify as a second label. The intermediate of formula 4 also meets the claim language.

The traverse is unpersuasive. The definition in R2, option (e), allows two carbons to be replaced with a saturated heterocycle. The same reasoning applies, with for example the P being detectable via P31 NMR. Claim 12 is included because the sugar-type residue qualifies as a substituted heterocycle, meeting the amended definition for R5.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., ***In re Berg***, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); ***In re Goodman***, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); ***In re Longi***, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); ***In re Van Ornum***, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); ***In re Vogel***, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and ***In re Thorington***, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 4-22, 44-47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 4, 5, 8-19, 21-25, and 29-31 of copending Application No. 10529651. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is no line of demarcation between the cases. The reasons were given previously.

The traverse is unpersuasive. The issues are generally the same. Note that saccharides when cyclic (e.g. as in lactose) meet the R5 definition as well as a substituted heterocycle. Even the alkyl (larger than methyl) will meet the definition as the protons can be seen in PMR and their stretch vibrations can be seen in IR.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 4-22, 44-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. The phrasing "oligomer or short term polymers of 6-50 subunits" is unclear, Since these terms seem to overlap. 6-50 would be considered oligomers. Does applicant intend nothing higher than 50? In other words, is "oligomers" to be understood as not covering 50? Does it cover 6? Do applicants intend smaller than 6?

2. In the oligomer/polymers, the text is indefinite. It says what is attached to the subunit, but does not say what the subunit itself is. Likewise claim 22.
3. Moreover, the pendent guanidinium groups are indefinite. These groups bear a charge. There must be a balancing group (or groups) somewhere to make the molecule neutral. Something has been left out.
4. The last L1/L2 choice is oddly in the plural, which makes no sense, since L1 is just a single thing. Note that the others are all singular. Likewise claim 22.
5. In choice (e) for R2, the term "bridging" is unclear. Since this is a linking group (divalent), every atom is part of a bridge. How would the claim be different if it were removed. In this regard, applicants remarks with regard to point 5 but this language does not convey this. The suffix "-ene" does convey this, as it means divalent, but if not appropriate, applicants can use "divalent" itself, which means the same thing as "-ene".
6. The "optionally containing substituents" text at the end of the R2 def is unclear. Is this optional feature just part of option (f)? Does it apply to any of (a)-(f) or does it apply even if none of (a)-(f) are being employed. And what are these substituents? The examiner sees not guidance in specification.
7. What is "active ester? Ester of what sorts of acids? Active how?
8. It is unclear how small these "parts" of the sequence can be. Taken literally, this could be as small as the SH of Cy or the pyrrolidine ring of Pro, etc. All of these are parts of the sequence.
9. Claim 44 is very unclear. It is unknown what "manipulating" is supposed to cover. The traverse is unpersuasive. Applicants point to the fact that it is in the preamble. But the only manipulating the claim sets forth is the actual step, which only says

"manipulated", and even that is only optional. That is, while there is a required detection step, there is no required manipulation step; that is optional. Thus, the claim reads on a method of manipulating, without even the "manipulated" being required. Moreover, one still does not know what the manipulating is supposed to consist of. A generic definition of this very broad term, from a non-technical source, is of no value. The claim does now have a "fusion" step, but it is unclear whether "manipulating" means only fusing, or if it means something broader.

10. The scope of AGT (O(6)-Alkylguanine-DNA alkyltransferase) is unclear. Is it just human AGT intended? AGT is found in organisms as diverse as bacteria and archaeons. The traverse is unpersuasive. Applicants have not actually addressed this specific question.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark L. Berch/
Primary Examiner
Art Unit 1624

6/14/2010